CHAPTER **43**

SUBJECTIVE ANALYSIS OF THE EFFECTIVENESS OF EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT)

Jana Poock, DPM
Erica Torgrude, DPM
Jeffrey Boberg, DPM

Heel pain is one of the most common aliments affecting the foot. It accounts for approximately fifteen percent of all patient complaints that enter the podiatrist office each year.[1] The etiologies of heel pain are numerous, although the diagnosis of plantar fasciitis is the most frequently encountered. Estimates state that more than two million people receive treatment for plantar fasciitis in the United States each year.[2]

The traditional approach to the treatment of plantar fasciitis has both a conservative and surgical component. Conservative treatment for plantar fasciitis has a high success rate and includes but is not limited to the following: strapping, icing, ultrasound, stretching, corticosteroid injections, physical therapy, orthotics, modifications in shoe gear, and night splints. Surgical treatment for plantar fasciitis also with a high success rate can be categorized into three approaches: neurolysis, heel spur resection, and plantar fasciotomy.[3]

Within the past few years, a new treatment option for plantar fasciitis has been increasing in popularity. This treatment option is extracorporeal shock wave therapy (ESWT), and was first used for the treatment of soft tissue pain in proximity of bone by Admen in 1992.[4] At this time more than 30 different chronic syndromes have been treated with 52% of the patients having good results, 28% improved and only 3% requiring surgery.[4] Since this first attempt, ESWT has become much more common for the treatment of plantar fasciitis. Currently, a device such as the OssaTron‰ unit is used to generate shock waves created by a spark plug enclosed in a plastic dome of water. The energy from these shock waves is focused at the point of maximum pathology. The exact mechanism by which the ESWT therapy works is not fully understood but the resulting inflammation of the shock wave is believed to stimulate a healing inflammatory response.

Preliminary research has been published on the results of ESWT therapy for the treatment of plantar fasciitis. Weil, et al completed research on ESWT for the treatment of chronic plantar fasciitis using 1500-3000 pulses at 17-21kV. This study included 36 patients with plantar fasciitis symptomatic for greater than 6 months, and the follow up was a mean of 8.4 months. They documented an overall mean percentage of improvement of 78.1 and a satisfaction rate of approximately 80%. Additionally, they reported 50% of the patients had greater than 50% improvement on a visual analog scale.[5] A similar study using 3000 shockwaves at 0.2mJ/mm2, increased the amount of shock waves by giving 3 sessions of 3000 shockwaves at weekly intervals. After 3 months, 64% of the patients had decreased pain at rest, daily life activities pain decreased by 71%, pain during single leg stance decreased by 64%, and pain from thumb pressure on the heel decreased by 65%. Overall, 6 months after ESWT therapy a 64-88% decrease of pain was noted on a visual analog scale.[6]

Long-term follow-up results of ESWT therapy are also of interest. A one-year follow-up study was completed in which 79 patients received 1-3 treatments of 1000 shockwaves at 14kV. Overall they reported 75.3% of their patients were complaints-free, 18.8% were significantly better, 5.9% were slightly better, and none were unchanged or worse. A 5% recurrence rate was noted after 15 months post-treatment.[7] A similar study with a one-year follow-up utilizing 1000 shockwaves on 20 patients reported that 90% were improved or pain-free. Subjectively, 90% of the patients said they would undergo the procedure again if pain persisted.[8]

The amount of shockwaves required to have pain relief has also been questioned. Rompe, et al studied two groups of patients, one treated with 3 applications of 1000 impulses and one treated with 3 applications of 10 impulses. They found little to no improvement with 10 impulses as compared to the 1000 impulses, concluding that more impulses must be administered to be effective.[9]

The duration of symptoms and the success of ESWT therapy has also been documented in the literature. Helbig, et al completed a study on patients with epicondylitis of the distal humerus and patients with plantar fasciitis. They reported that patients who had

symptoms for greater than 35 months had the most effective pain relief from ESWT therapy, while the worst results occurred in patients with a pain duration of 3-12 months. They concluded ESWT therapy is most effective for patients in a more chronic state.[10]

Ogden, Alvarez and Marlow performed a meta-analysis of the available literature to assess the biologic and therapeutic effects of ESWT therapy and credibility of these published studies. They reviewed 20 published studies, eight of which fulfilled their criteria for acceptable studies of sufficient duration (one year or more after treatment). They found overall success rate of ESW therapy as high as 88%.[11]

The most recent and most controversial study was published in the Journal of American Medical Association. In this study, patients given ultrasound-guided ESWT therapy were evaluated against a group of patients receiving a placebo. No evidence was found to support the benefit of ESWT therapy over the placebo, as a result they concluded that ESWT therapy was not effective for the treatment of plantar fasciitis.[12] Although the dosage of ESWT used in this study was only a total of 1000mJ/mm2 given over a 3 week time period. This low level of energy shockwave is not considered therapeutic for the treatment of plantar fasciitis.

The overall success of ESWT therapy for the treatment of plantar fasciitis is still undetermined. The purpose of this study was to more clearly define by subjective analysis the effectiveness of ESW therapy for the treatment of plantar fasciitis. This study evaluates the most important aspect of patient care, the opinion of the patient. It evaluates the viewpoints of the patient on the overall success of ESW therapy.

MATERIALS AND METHODS

This was a retrospective study involving 22 patients from October 2001 to September 2002. The patients involved in this study had heel pain consistent with plantar fasciitis for at least six-months. These patients, after a myriad of conservative therapy generally consisting of injections, ultrasound (US), strapping, orthotics, stretching, NSAIDs and plantar fascial bracing, underwent the OssaTron‰ procedure. Our inclusion criteria consisted of patients which were diagnosed with chronic plantar fasciitis, had underwent non-operative management for at least six months, had failed conservative therapy, and were at least 21 years of age and skeletally mature. Our exclusion criteria included patients that had undergone prior surgery for this condition, patients with less than six-months of symptoms and conservative treatment, patients without pain on palpation of the plantar heel, patients with vascular insufficiency or neuropathy, and patients with gross pathologic problems in their feet such as osteoporosis, arthritis, malignancies, or infections.

DESCRIPTION OF THE PROCEDURE

Before the procedure the patient's heel was examined determining the point of maximum tenderness. This area was marked with a skin marker for reference during the procedure. The anesthesiologist then induced light general anesthesia utilizing a mask to maintain an airway. A local infiltration block of 5ccs of 2% lidocaine plain was then instilled to the affected heel.

With the patient in the supine position, the foot was then positioned in a manner that the patient's affected heel was in contact with the ellipsoid dome of the OssaTron unit. Coupling gel was then applied to the interface between the foot and the OssaTron unit to allow for proper transmission of the shockwaves. Next utilizing the OssaTron unit, 1,500-1,600 shockwaves at an intensity of 18kV were administered to the heel. During the procedure, the physician occasionally repositioned the foot to insure the shockwaves were penetrating the area of maximum tenderness, which was determined before the start of the procedure.

Following the procedure, an additional local infiltration block of 3ccs of 0.5% marcaine plain was instilled to the patient's affected heel. As well as, 1cc of dexamethasone (4mg) was injected into the point of maximum tenderness. The patient was then transported to the recovery room and discharged by a member of the department of anesthesia. Post-treatment care included protective ambulation in a walking boot, and return to normal shoegear, full weightbearing, and normal activity within two weeks. Patients were advised to continue their pre-treatment conservative care regimen as needed for discomfort.

ACCUMULATION OF DATA

All patient's charts were reviewed to obtain the type of conservative treatment, duration of symptoms, patient's demographic data, and if additional procedures were performed post OssaTron procedure. A phone survey was then performed. Prior to the survey patients received an informational letter, which included a copy of a visual analog pain scale. The telephone survey requested patients to rate their morning heel pain and average daily heel pain levels on a scale of 0-10 prior to OssaTron‰ and at present. They were also asked to rate the activity

limitations of their heel pain on a scale of 1-5. Further questions asked were: how satisfied they were with the procedure, if they had to do it over, would they undergo the procedure again, and would they recommend this procedure to others. Finally, they were asked to give an overall percentage of how much better they felt as compared to before the procedure.

RESULTS

A total of 22 patients were included in this study with a total of 23 feet (one bilateral) and a total of 27 procedures (4 with a second procedure) performed. These four patients remained symptomatic for at least 4 months after the procedure, and elected to have the procedure repeated. The additional procedure was completed in the same manner as the first procedure. The post-procedural care was also identical to the first procedure.

There were 12 left feet (52.2%) and 11 right feet (47.8%) involved with the initial procedure. There were 18 female (82.6%) and 4 male (17.4%). The age ranged from 22 to 67 with 48 being the average age. The duration of symptoms ranged from 6 months to 112 months (9 years 4 months) and the average duration of symptoms was 17 months. There were six patients that underwent additional procedures, four of which underwent an additional OssaTron‰. Of these four, two went on to surgery approximately 2 to 3 months post-2nd OssaTron‰ which consisted of plantar fasciotomy with heel spur resection. The other two went to surgery approximately 3 to 4 months post-OssaTron‰.

Prior to the procedure the average morning pain ranged from 3 to 10 with the average being 7.7. Average daily pain ranged from 4 to 10 with an average of 7.6. Activity limitations ranged from 2 to 5 with average being 3.9. The duration from the OssaTron‰ procedure to the time of the phone survey ranged from 3 to 12 months with an average of 8 months. The post-procedure data is as follows: morning pain ranged from 0 to 8.5 with an average of 2.65. The average daily pain ranged from 0 to 5.5 with an average of 3.2. Activity limitations ranged from 1 to 4 with an average of 2.130. An overall percent better averaged at 71.13%, ranging from 25 to 100%

As far as considerations and subjective opinion of the procedure itself, 43.48% were very satisfied, 21.74% were satisfied, 26.09% were dissatisfied, and 8.70% were very dissatisfied. This calculates out to 65.22% overall being generally satisfied with the procedure. 73.91% of the patients stated that if they had to do it over they would undergo the procedure again, whereas 26.09% would not, with the most common reason being that it did not meet their expectations. 95.65% of the patients said they would recommend the procedure to others with heel pain, whereas 4.35% said they would not because they didn't know if it would help others because it didn't help them.

The patients that underwent an additional OssaTron‰ procedure were also evaluated. Their average duration from the first OssaTron‰ procedure was 3.625 months and range from 1 to 7 months. Their average morning pain was again rated post procedure and was found to have ranged from 1 to 8 with an average of 4. The average daily pain ranged from 1.5 to 7 with an average of 5.125. Their activity limitations ranged from 1 to 4 with an average of 3. These patients were 50% better on an overall average, which ranged from 20% to 90%.

DISCUSSION

From a subjective point of view we were able to assess some of the patient's expectations with this procedure, and obtain a better understanding of public opinion on the procedure itself. Most of the dissatisfaction felt by the patients with regards to the success of the procedure was due to high expectations. Many patients expected to be pain free with this procedure and expected no return of symptoms. In a few rare cases (three out of 23 or 0.13%) this was accomplished. A couple of patients who reported good results didn't attribute these results to the procedure itself. One patient stated it was more the education and continued conservative therapy administered from the physician. The other patient stated that shortly after the procedure her activity level significantly decreased because she had retired. Overall, we found that the patients liked the non-invasiveness, quick recovery and limited pain benefits of the procedure itself. Even though the patients may not have had success with the procedure they would still recommend it to others. One patient (who eventually underwent surgery) even stated that although they were dissatisfied with the results, they were satisfied with the procedure and recovery process much more so than the surgery. They further stated they would recommend it to others before having surgery, in an attempt to improve one's symptoms.

These results do not compare quite as favorably to previous reported studies, as noted earlier. All patients in this study had the heel injected pre-procedure with local anesthesia and had corticosterioid injected directly afterwards. Whether the effect of increased fluid content in the heel prior to ESWT had any effect on the delivery of energy to the fascia is unknown. Additionally, the anti-inflammatory effect of the injected corticosteroid may

block the therapeutic effects the sound energy.

In conclusion we found patients to be overall 71% better with a significant decrease from pre to post procedure pain and activity limitations. We feel that obtaining complete pain relief with this procedure is highly unlikely. Although many patients showed improvement of their symptoms, only 0.13% of the patients were without symptoms. This supports the fact that although ESWT reduces symptoms it is most likely not a cure.

It provides an alternative to surgery, with quicker recovery and less if any post-operative pain. This is especially an important consideration since the majority of these patients are highly active and would prefer a quicker return to work, recreational activities, and normal shoe gear. These elements are important for patients and are exhibited in the high degree of satisfaction that patients had with the procedure. It is also evident in that nearly all of the patients in this study would recommend the procedure to others with plantar heel pain.

Plantar fasciitis remains a frequently encountered diagnosis in the podiatric community. Conservative measures although many in number do not always cure the patient of their symptoms. ESWT presents a non-invasive, and practically risk and complication free method to reduce plantar heel pain.

REFERENCES

1. McCarthy DJ, Gorecki GE. The Anatomical Basis for Inferior Calcaneal Lesions. *J Am Pod Assoc* 1979;69:527-36.
2. Pfeffer, G. et al. Comparison of custom and prefabricated orthoses in the initial treatment of proximal plantar fasciitis. *Foot Ankle Int* 1999;20:214, 1999.
3. Boberg J, Dauphinee D. *McGlamry's Comprehensive Textbook of Foot and Ankle Surgery,* 3rd edition Philadelphia. Lippincott Williams & Wilkins, 2001:464-476.
4. Haupt G. Use of Extracorporeal Shock Waves in the Treatment of Pseudoarthrosis, Tendinpathy and Other Orthopedic Diseases. *J Urology* 1997;158:4-10.
5. Weil LS, et al. Extracorporeal Shock Wave Therapy for the Treatment of Chronic Plantar Fasciitis: Indications, Protocol, Intermediate Results, and a Comparison of Results to Fasciotomy. *J Foot Ankle Surg* 2002;41:166-72.
6. Hammer D, et al. Extracorporeal Shockwave Therapy (ESWT) in Patients with Chronic Proximal Plantar Fasciitis. *Foot Ankle Int* 2002;23:309-13.
7. Wang C, et al. Shockwave Therapy for Patients with Plantar Fasciitis: A One-Year Follow-up Study. *Foot Ankle Int* 2002;23:204-7.
8. Alvarez R. Preliminary Results on the Safety and Efficacy of the OssaTron for Treatment of Plantar Fasciitis. *Foot Ankle Int* 2002;23:197-203.
9. Rompe J, et al. Evaluation of Low-Energy Extracorporeal Shock-Wave Application for Treatment of Chronic Plantar Fasciitis. *J Bone Joint Surg Am* 2002;84:335-41.
10. Helbig K. Correlations Between the Duration of Pain and the Success of Shock Wave Therapy. *Clin Orthop Rel Res* 2001;387:68-71.
11. Ogden, J, et al: Shockwave Therapy for Chronic Proximal Plantar Fasciitis: A Meta-Analysis. *Foot Ankle Int* 2002;23:301-7.
12. Buchbinder R, et al. Ultrasound-Guided Extracorporeal Shock Wave Therapy for Plantar Fasciitis. *J Am Med Assoc* 2002;288:1364-72.